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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,355	11/08/2001	Alexander B. Rossi	A-70882/RMS/AMS	5867

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,355	ROSSI, ALEXANDER B.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-58,60-75 and 77-80* is/are pending in the application.

4a) Of the above claim(s) *40,41,54,55 and 71-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-39,42-53,56-58,60-70 and 77-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed 4/19/04 have been entered. Claims 51 and 64 have been amended, and claims 59 and 76 have been canceled. Claims 37-58, 60-75, and 77-80 are pending.

As an initial matter, because applicant did not distinctly and specifically point out the supposed errors in the modified restriction requirement in the Office action mailed 1/14/04, the election has been treated as an election without traverse (MPEP § 818.03(a)). Election was made **without** traverse in the Paper dated 4/19/04. Claims 37-39, 42-53, 56-58, 60-70, 77-80 are under current examination.

This application contains claims (40, 41, 54, 55, 71-75) drawn to an invention nonelected without traverse in the reply filed on 4/19/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claim 66 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 66 requires the cells in the substantially pure mast cell population are at least 10^7, whereas the base claim from which it depends from requires the cells are at least 10^8, thus the dependent claim fails to further limit the previous claim. Applicant is required to cancel

the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64-66 stand rejected and Claims 51-53, 56-58, and 60-63 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim (64) recitation, "substantially pure", applicants argue that the term is definite when viewed in light of the specification, and citing means of identifying mast cells disclosed in the specification as support. The arguments are not persuasive, because the subject matter at issue is not whether one knows how to identifying a mast cell, but the degree of purity the claim cell population embraces. For example, what percentage of mast cells in a population of mixed cells is considered as "substantially pure"? Since no criteria is set forth, the metes and bounds of the claims are unclear.

The amended claim 51 is drawn to a population of cultured mast cells "comprising as least 10^8 cells". As evidenced in claims 37 and 60-63, the population of cultured mast cells comprises at least two types of cells, the proliferated population of progenitor cells and proliferated mast cells. It is unclear what type of cells the newly

added "cells" refers to, the progenitors, the mast cells, or the total cells, thus the metes and bounds of the claims are uncertain. For the sake of a compact prosecution, and in light of the arguments presented in the Remarks, the "cells" will be interpreted as differentiated mast cells in this Office action.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The prior rejection of claims 51-53, 56-58, and 64-66 under 35 U.S.C. 102(b) as anticipated by *Saito et al* (Int Arch Allergy Immunol 1995;107:63-65, IDS) is withdrawn in view of claim amendment, and the rejection has been modified as following.

Claims 51-53, 56-58, and 64-66 are newly rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over *Saito et al* (Int Arch Allergy Immunol 1995;107:63-65, IDS).

The amended claims 51 and 64 are drawn to a population of cultured mast cells comprising as least 10^8 mast cells.

Saito et al teach that they generated more than $5x10^7$ mast cells from $5x10^7$ cord blood mononuclear cells (page 64, 1st paragraph). Here, "more than $5x10^7$" encompasses "at least 10^8". Moreover, even if the mast cells taught by *Saito et al* are less than 10^8, given the knowledge of the skilled, if more than 10^8 mast cells are needed, one could set up multiple cultures of cord blood MNCs and combine the generated mast cells to obtain a population of mast cells comprising at least 10^8 mast cells. Thus, the claimed mast cell population as a whole was anticipated or *prima facie* obvious in the absence of evidence to the contrary.

In the Remarks, Applicants contend Saito describes generating a population of about 5×10^7 cells, but not at least 10^8 cells, and that through use of flt-ligand and stem cell factor prior to differentiation into mast cells allows generation of mast cell numbers exceeding those described in Saito (Remarks, the last two paragraphs of page 7).
In response, *Saito et al* use the phrase more than $5x10^7$ mast cells, not "about". Since more than $5x10^7$ encompass at least 10^8, it is applicants burden to prove with factual evidence that there is less than 10^8 cells in the cell population disclosed by *Saito et al*. Applicants are reminded that the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the prior art products do not necessarily or

inherently possess characteristics of claimed product, which requires factual evidence demonstrating that actual, unobvious differences exist (or that the claimed products are functionally different than those taught by the prior art) and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPBI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922, 1923 (BPAI 1989).

With respect to limiting the population of mast cells by the number of cells, it is noted regardless the total numbers of the mast cells in the population, as long as the characteristics of these cells are the same, one can easily manipulate the total number of mast cells in the population by increasing or decreasing the starting cell population or setting up multiple parallel cultures.

The prior rejection of claims 51-53, 56-58, 64, 65 under 35 U.S.C. 102(b) as being anticipated by *Kirshenbaum et al* (Blood 1999;94:2333-42, IDS) is withdrawn in view of claim amendment, and the rejection has been modified so that these claims are now rejected under ***35 USC § 103***.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-53, 56-58, 60-66 are newly rejected under 35 U.S.C. 103(a) as being obvious over *Kirshenbaum et al* (Blood 1999;94:2333-42, IDS).

The amended claims 51 and 64 are drawn to a population of cultured mast cells comprising as least 10^8 mast cells, wherein the proliferated progenitor cells are between 10^7-10^{11}.

Kirshenbaum et al generated about $2x10^6$ mast cells from $5x10^4$ CD34+ progenitor cells (page 2334, left column). Although the numbers of mast cells described by *Kirshenbaum et al* do not reach the amount as recited in the instant claims, given the knowledge of the skilled, if more than 10^8 mast cells are needed, one could set up multiple cultures of cord blood MNCs and combine the generated mast cells; or increasing the number of the cells in the starting cell population to obtain a population of mast cells comprising at least 10^8 mast cells. Thus, the claimed mast cell population as a whole was *prima facie* obvious in the absence of evidence to the contrary.

In the Remarks, Applicants contend *Kirshenbaum et al* describe generating a population of about 10^6 cells, but not at least 10^8 cells.

With respect to limiting the population of mast cells by the number of cells, it is noted that it is within the levels of the reasonably skilled to manipulate the total number

of mast cells in the population by increasing or decreasing the starting cell population or setting up multiple parallel cultures to obtain a population of mast cells comprising at least 10^8 mast cells. Thus, the claimed mast cell population as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 37-39, 42-53, 56-58, 60-66 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Saito et al* (J Immunol 1996;157:343-50, IDS), taken with *Zhang et al* (Chin J Biotechnol 1999;15:189-94, IDS).

With respect to the method of cultivation of mast cells, Applicants argue that Saito does not teach or suggest treating CD34 positive cells with SCF and flt-3 ligand, does not teach an initial step for proliferating CD34+ cells into progenitor cells prior to conversion into mast cells. Applicants also contend that Zhang provide no teach or suggestion for contacting the expanded cells with SCF and a cytokine to generate functional mast cells, that Zhang et al never distinguishes the cell populations treated with SCF+flt-3 from those treated with SCF+flt-3+IL-3, other than the ability to form colonies of CFU-GM. Applicants go on to argue that as with Saito, Zhang is limited to a single step procedure, and concluded that at best, the combination would lead one to contact SCF, flt-3 ligand, IL-3 and/or IL-6 in a single step produce (Remarks, 4th paragraph page 9 through 2nd paragraph, page 10).

The arguments have been fully considered but found not persuasive for reasons of record and following.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, *Saito* reference is relied upon as a showing that it is known in the art for generating human mucosal mast cells by contacting CD34+ cells with human stem cell factor and human IL-6 (§Cell culture, page 344), and the purified CD34+ cells are prepared from human cord blood (§Cell preparation, page 344). *Zhang et al* supplemented *Saito et al* by pointing out the need for generating a large number of stem/progenitor cells in the art, and more importantly, by providing a solution to meet the need, i.e. using the combination of SF and flt-3 ligand (abbreviated as FL). *Zhang et al* teach "A MAJOR DEFICIENCY IS THE RATHER LOW CELL NUMBER AVAILABLE", "FL SYNERGIZED WITH SCF AND OTHER CYTOKINES", "IN ALL CONDITION INVESTIGATED, CULTURES WITH FL OBTAINED AN INCREASE OF FOLD EXPANSION IN BOTH TOTAL CELLS AND CFU-GMS" (abstract).

Zhang reference is devoted to the influence of flt-3 ligand on *ex vivo* expansion of cord blood progenitor cells. Here, IL-3 is used as an indicator for population expansion potential. This is taught in the last paragraph of page 191, where *Zhang et* al teach that use of FL or SCF alone, no increase of total cells could be observed while with addition of IL-3, cells obviously expanded (see also figure 1). The effects of the combination of SCF and flt-3L could be seen in figure 1, when one compares the value of the top bar with that of the third bar from top, the effects of the combination of SCF and flt-3 ligand on cell expansion or total numbers of cells are clearly depicted, i.e. compared to the

group without SCF and flt-3L, the total number of cells in FL+SCF treated group increased about 10 folds, and exceeded 10^{11} cells. *Zhang et al* go on to explain the significance of the observation, "BOTH CYTOKINES (SCF and FL) MAINTAINED THE ACTIVITIES OF STEM/PROGENIOTR CELLS AND HAMPERED DIFFERENTIATION". Applicants are also reminded that the "CFU-GMs" criteria was used by *Zhang et al* as an indicator for the numbers of progenitor cells in the cell population which reflects the proliferation potential of the cell population ("CFU-GMS WERE LINEARLY CORRELATED WITH NUMBERS OF HEMATOPOIETIC STEM CELLS", "WE ASSAYED CFU-GMS TO ASSESS THE PROLIFERATION POTENTIAL OF CORD BLOOD MNCS", 3rd paragraph, page 190). Apparently, *Zhang et al* clearly teach that treating CD34+ cord blood cells with SCF+flt-3 would increase or potentiate the stem/progenitor cells, which equals to the initial step recited in the claims.

It is noted that obtaining sufficient number of stem/progenitor cells is naturally a separate issue from how to use the stem/progenitor cells. It would have been obvious to use them for either direct transplantation or further differentiation. To this end, *Zhang et al* suggested to use the progenitors (HSC) for further differentiation into various mature blood cell types and citing the differentiation to mast cells by SCF+IL-6 as an illustrated embodiment (reference 5 of *Zhang et al*), which would be the second step recited in the instant claims.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods taught by *Saito et al* and *Zhang et al* by including flt-3L in the cytokine regimen taught by *Saito et al*, and utilizing the synergistic effect of SCF and flt-3 as taught by *Zhang et al* in the preparation of mast

cells to maximize the mast cell expansion with a reasonable expectation of success. Regardless whether the steps were separated or combined, a significant increase in stem/progenitor cell potential would be reasonable expected as illustrated in figure 1 of *Zhang et al*. The fact that using one-step culture, *Zhang et al* obtained more than 10^{11} cells further supports that the expectation of success is reasonable. The ordinary skilled artisan would have been motivated to modify the method to arrive at the claimed invention because it is known that flt-3 synergizing the effect of SCF in expanding progenitor cells, and it is known SCF and IL-6 could differentiating the stem cells to mast cells, thus, the combination would enhance mast cell production by one step or two steps. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 19880; *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Thus, for reasons of record and set forth foregoing, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 67-70, and 77-80 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Saito et al* (J Immunol 1996;157:343-50), and *Zhang et al* (Chin J Biotechnol 1999;15:189-94) as applied to claims 37-39, 42-53, 56-66 above, and further

in view of *Demo et al* (Cytometry 1999;36:340-8) and *Janaki et al* (J Ethonopharmacol 1999;67:45-51).

In the Remarks, Applicants contend that neither Demo nor Janki describes using a proliferated population of mast cells comprising at least about 10^8 cells.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, it is the combined teachings of *Saito et al, Zhang et al, Demo et al,* and *Janaki et al* that rendered the claimed invention obvious. One may not need that many mast cells to conduct the screening assay as taught by *Demo et al* and *Janaki et al*, or if more than 10^8 mast cells are needed, given the knowledge of the skilled, one could set up multiple cultures of cord blood MNCs and combine the generated mast cells; or increasing the number of the progenitor cells in the starting cell population to obtain a population of mast cells comprising at least 10^8 mast cells. Thus, the claimed mast cell population as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-39, 42-53, 56-58, 60-70, 77-80 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the Remarks, Applicants argue that the specification shows that mast cells made by the claimed method display all the characteristics of functioning mast cells, and contend that the standard asserted by the Examiner is neither prescribed in the MPEP or by the courts.

In response, the subject matter at issue is not whether the cells made by the method are functioning mast cells but the type of mast cells. The standard in MPEP under 35 U.S.C. §112, first paragraph entails that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). The court states that "THE DISCLOSURE OF A PATENT APPLICATION MUST ENABLE PRACTICE OF THE INVENTION CLAIMED WITHOUT UNDUE EXPERIMENTATION" ((*Ex parte Forman*, 230 USPQ 546,547 (BPAI 1986)). Accordingly, the claims will be evaluated by the standard.

The elected inventions for examination are drawn to a population of *mucosal* mast cells and a method of making such. Thus, when analyzing the enablement of the claims, the phenotype of the claimed product or the phenotype of the end product of the claimed method is rightfully the subject to be considered because the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the

specification. As cited above, both the MPEP and the court decisions support the standard used by the Office. Further, the Office has provided several prior art of record showing that it is ambiguous with regard to the phenotype of SCF+IL-6 treated mast cells. *Matsushima et al* (J Dermatol Sci 2000;24:4-13) teach that according to electron microscopic observation, these cells are so immature that they could not distinguish MCT and MCTC based on the ultrastructural morphology, they concluded that SCF and IL-6 do not develop fully mature mast cells *in vitro* (abstract). *Saito et al* teach that cultivated population are 99% positive for tryptase, and 18% chymase (which is suppose to be negative for mucosal mast cells, 2nd paragraph, left column, page 349), thus, it appears that a mixed population including mucosal and other types of mast cells is produced. *Ahn et al* (J Allergy Cin Immunol 2000;106:321-8) teach that tryptase-positive cultivated mast cells can give rise to tryptase and chymase double-positive MCs (abstract). *Kinoshita et al* (Blood 1999;94:496-508) teach that SCF+IL-6 would cause substantial increases in the frequency of chymas-positive cells (see abstract) whereas mucosal mast cells are chymas-negative. The specification acknowledges such uncertainty and teaches that even though reports from prior art of record such as *Saito et al* teach that SCF and IL-6 could differentiate mast cells from CD34+ cells, reports from different groups indicated that prior methods have produced variable results (Specification, paragraph bridging pages 3-4). Accordingly, it is applicants duty to provide sufficient and enabling teachings within the specification to clarify the variable results and advance the knowledge lacking in the prior art of record. However, the specification fails to shed light on such ambiguity in the prior art, because it fails to

describe the phenotypes of mast cells produced by the claimed method, and thus fails to provide an enabling disclosure to support the full scope of the claims.

Applicants go on to argue that specification met the enablement requirement by specific disclosure for sources of CD34 positive cells, and the factors needed such as SCF and IL-6.

In response, these conditions are known in the art as taught by the cited art of record such as cited in *Saito et al, Matsushima et al, and Kinoshita et al* for differentiating mast cells, yet the art of record raised doubt on the phenotype of the generated mast cell population, i.e. whether they are mature so that the phenotype could be identified, e.g. whether they are mucosal or connective tissue mast cells, or whether they are substantially pure mucosal type. In view of such, the invention does not appear to be enabled in the absence of clarification of the contradictory evidence found in the references.

Accordingly, for reasons of record and set forth above, the specification fails to meet the statutory enablement requirement.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JANICE LI
PATENT EXAMINER

Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
June 21, 2004